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**IN RE PHARMACEUTICAL INDUSTRY
AVERAGE WHOLESALE PRICE
LITIGATION**

THIS DOCUMENT RELATES TO

*State of Nevada v. American Home Prods. Corp.,
et al.*, 02-CV-12086-PBS

State of Montana v. Abbott Labs., Inc., et al., 02-
CV-12084-PBS

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Hon. Patti B. Saris

Defendant Aventis Pharmaceuticals Inc. (“Aventis”) respectfully submits this memorandum of law, in support of its motion pursuant to Fed. R. Civ. P. 56(b) for partial summary judgment on all claims relating to Aventis’s self-administered drugs asserted by the States of Montana and Nevada.¹

Plaintiffs allege that Aventis (i) “controlled and set the AWP’s for all of its drugs . . . through direct communications with industry compendia,” (ii) engaged in a “scheme to inflate its reported AWP’s,” and (iii) engaged in a scheme to “market the resulting spread to increase the market share of its drugs.” Plaintiffs allege that this conduct “has resulted in excessive

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overpayments” by the States of Montana and Nevada and their citizens. (State of Montana’s Second Amended Complaint (“MSAC”) at ¶¶ 276-277; State of Nevada’s Amended Complaint (“NAC”) at ¶¶ 221-222.)² The State of Montana alleges that Aventis’s alleged conduct violated the State’s Unfair Trade Practices Act, MONT. CODE ANN. § 30-14-101 *et seq.*; Medicaid Fraud statute, MONT. CODE ANN. § 53-6-160 *et seq.*; and False Claims Act, MONT. CODE ANN. § 17-8-231 *et seq.* Similarly, the State of Nevada claims that Aventis violated the State’s Deceptive Practices Act, NEV. REV. STAT. §§ 598.0903 *et seq.*, and Medicaid Fraud statute, NEV. REV. STAT. §§ 422.540 and 422.580.³

The Court should grant Aventis’s motion for summary judgment on all claims relating to self-administered drugs because the undisputed facts show that:

- (i) Aventis has not suggested AWP’s for its products since 2001. Before that time, Aventis suggested AWP’s which reflected a fixed percentage mark-up over its wholesale list prices based on industry standards. Additionally, Aventis limited the list price increases of its product portfolio to an amount approximating increases in the Consumer Price Index (“CPI”).
- (ii) Aventis reported wholesale list prices that reflected actual prices for its self-administered drugs.
- (iii) Aventis did not “market the spread” or in any way use reported AWP’s to increase its market share for self-administered drugs.

² Plaintiffs also allege that Aventis and other defendants encouraged physicians to bill Medicaid for free goods, but there is no proof of that and plaintiffs appear to have abandoned that claim.

³ All other claims previously asserted against Aventis have been dismissed. *See In Re Pharm. Indus. AWP Litig.*, 321 F. Supp. 2d 187, 208 (D. Mass. 2004).

Given these undisputed facts, no reasonable jury could find that Aventis violated any of the statutes at issue in these cases by engaging in deceptive or unfair conduct that injured the States of Montana or Nevada or their citizens.

STATEMENT OF FACTS

A. Aventis Pricing

Plaintiffs' expert, Dr. Hartman, has analyzed and purported to find liability with respect to the following Aventis self-administered drugs: Allegra, Allegra-D, Amaryl, Arava, Azmacort, Carafate, Cardizem, Cardizem SR, Intal, Nasacort, Nasacort AQ, and Trental. All of these products were "single source," branded, self-administered medications during the entire relevant period.⁴ (Statement of Undisputed Material Facts ("SUMF") at ¶ 1.)

For the self-administered drugs at issue here, Aventis sets a list price, called at various times Wholesale List Price ("WLP") or Wholesale Acquisition Cost ("WAC"). These list prices are reported to Aventis's customers and to the industry pricing compendia. After launch, Aventis may periodically raise the list prices for its drugs. The Aventis Pricing Board established guidelines to be followed to insure that the company stays within the CPI for its overall weighted averages of price increases across the entire portfolio of products. Aventis refers to this policy as the "Belle CPI," named after the then-president of its North American business unit, Gerald Belle. (SUMF at ¶ 11.) The commitment to keep price increases at or below the CPI was also followed by Aventis's predecessor companies.⁵

⁴ While this motion specifically seeks summary judgment on plaintiffs' claims relating to Aventis's self-administered drugs, for the reasons outlined in defendants' joint memoranda of law in support of summary judgment, summary judgment should also be granted on all claims relating to Aventis's two physician-administered drugs at issue, Anzemet and Taxotere.

⁵ Aventis was formed on December 15, 1999 from the merger of Hoechst Marion Roussel ("HMR") and Rhone-Poulenc Rorer ("RPR").

Aventis sold virtually all its self-administered drugs to wholesalers, who then resell the products to their customers, such as retail pharmacies. (SUMF at ¶ 13.) Aventis recorded these sales at the wholesale list prices reported to the pricing publications and others. These list prices were then adjusted to take into account any customer discounts. For example, most wholesalers and direct purchasing chain pharmacies received a two percent prompt pay discount when they paid for the products within a specified time period. (SUMF at ¶ 15.) Additional adjustments were made to the wholesale list price if the wholesaler resold the product to customers, such as hospitals, who had negotiated special pricing discounts with Aventis. In such cases, Aventis sold the drug to the wholesaler at the list price; the wholesaler then sold the drug to the customer at the discounted price; and the wholesaler then received a “chargeback” from Aventis that made it whole. (SUMF at ¶ 16.)

The vast majority of Medicaid reimbursements for self-administered drugs at issue in these cases were made to retail pharmacies who did not receive discounted pricing from Aventis. Thus, for the vast majority of transactions at issue here, Aventis’s net sales price for its self-administered drugs was either at or near wholesale list price. (SUMF at ¶ 17.) The data produced by retail pharmacies in these cases confirms that the pharmacies did not receive pricing discounts from Aventis for the drugs at issue and, as a result, they purchased the drugs at wholesale list price plus a small wholesaler mark-up (or mark-down). (SUMF at ¶ 18.)

B. Aventis Price Reporting

Prior to August 2001, Aventis and its predecessor companies reported two price benchmarks to the pricing publications: (1) an undiscounted wholesale list price, referred to either as WLP or WAC, and (2) a price that was marked up from that list price and described as either the Manufacturer’s Suggested Price (“MSP”) (beginning in 2000) or Average Wholesale

Price (“AWP”) (prior to 2000). (SUMF at ¶ 2.) The MSPs and AWP’s that were reported prior to August 2001 were calculated by adding either 20% or 25% to the product’s WLP.⁶ (SUMF at ¶ 3.) This AWP/MSP mark-up conformed to industry custom and practice. (SUMF at ¶ 6.)

Since 2000, Aventis has included in its price announcements the following disclaimer regarding WLP: “The list price may not reflect actual sales prices, which may include discounts, rebates, chargebacks, and other terms.” (SUMF at ¶ 7.) Beginning August 2, 2001, Aventis stopped reporting MSP. (SUMF at ¶ 8.) Since then, Aventis has reported only Wholesale List Price to its customers and the publishers, with the disclaimer that “the list price does not reflect discounts, rebates, chargebacks, or other terms or distribution arrangements that may reduce actual sales price.” (SUMF at ¶ 9.)

C. Aventis Marketing

Finally, there is no evidence whatsoever that Aventis “marketed the spread,” or even discussed AWP or reimbursement issues in connection with the marketing of Aventis’s self-administered drugs to providers reimbursed by Montana and Nevada.

ARGUMENT

The State of Montana has asserted claims against Aventis under the State’s Unfair Trade Practices Act, MONT. CODE ANN. § 30-14-101; Medicaid Fraud statute, MONT. CODE ANN. § 53-6-160; and False Claims Act, MONT. CODE ANN. § 17-8-231. The State of Nevada’s claims are based on that State’s Deceptive Practices Act, NEV. REV. STAT. §§ 598.0903 *et seq.*; and Medicaid Fraud statute, NEV. REV. STAT. §§ 422.540 and 422.580. The legal standards for establishing liability under each of these statutes is set forth in defendants’ joint memoranda of

⁶ Historically, AWP’s for branded pharmaceutical companies were usually set at a markup of either 20% or 25% above wholesale list price. Prior to the merger that created Aventis, RPR’s suggested AWP was equivalent to a 25% markup over list price, while HMR’s were set at 20%. For the short time after the merger that Aventis continued to report suggested AWP’s or MSPs, it maintained a markup over wholesale list price of 25% for all legacy RPR drugs and 20% for all legacy HMR drugs. (SUMF at ¶¶ 4-5.)

law in support of summary judgment, and will not be repeated here. Each statute, however, requires the State to establish that Aventis engaged in deceptive, unfair, and/or fraudulent conduct. The undisputed facts here establish that Aventis did not engage in conduct actionable under any of the applicable statutes with respect to the pricing, marketing, or sale of its self-administered drugs at issue in these cases.

A. Aventis's Pricing and Price Reporting Were Neither Deceptive, Unfair, Nor Fraudulent.

Plaintiffs can adduce no evidence to establish that Aventis engaged in deceptive, unfair, and/or fraudulent conduct with respect to the pricing or price reporting of its self-administered drugs. Since 2001, Aventis has reported only wholesale list prices which were at or very near the actual prices for the vast majority of drug sales that form the basis of plaintiffs' damage and penalty calculations. Plaintiffs' expert, Dr. Hartman, does not dispute this. In his June 13, 2006, declarations regarding the calculation of damages and penalties, Dr. Hartman stated: "For claims for reimbursement for single-source self-administered drugs . . . I understand that the retail acquisition costs (RAC) is approximately equal to WAC and indeed may be slightly less {that is, $RAC (EAC) < WAC$ }, perhaps 1-2% of AWP. To be conservative, I assume that $RAC = EAC \approx WAC$." (Hartman Montana Decl. of June 13, 2006 at ¶ 22(a) (attached to Matye Decl. as Ex. E); Hartman Nevada Decl. of June 13, 2006 at ¶ 23(a) (attached to Matye Decl. as Ex. F).) The data produced by retail pharmacies in these cases confirm that retail acquisition costs are very close to WAC, or wholesale list price, for the Aventis drugs at issue. And to the extent that discounts were taken off the wholesale list price, Aventis disclosed the existence and possibility of these discounts in its price announcements.

While Nevada and Montana case law provide little guidance on what makes a price "deceptive," other jurisdictions provide good authority on the subject. If a published price

is an actual price at which the product at issue is sold, then the publishing of that price is not a deceptive act. *See Abramovitz v. Paragon Sporting Goods Co.*, 608 N.Y.S.2d 432, 433 (N.Y. App. Div. 1994) (ruling that there was no violation of New York's deceptive trade practices act because defendant had presented evidence that the disputed prices were bona fide). If that published list price is subject to discounts by certain purchasers, that fact alone does not make the published price any less "true." The law regards such a "list price" as "the published or advertised price of goods which may change after negotiation and be reduced by a discount or rebate for prompt payment or volume purchase." *Davis v. Wholesale Motors, Inc.*, 949 P.2d 1026, 1040 (Haw. 1997) (citing Black's Law Dictionary 932 (6th ed. 1990)). It is, by definition, the published price of an item "before any discounts are taken." *Id.* (citing Merriam-Webster's Collegiate Dictionary 680 (10th ed. 1993)). Aventis's publication of list prices at which it made a substantial number of actual sales—and then disclosing that discounts may be taken from such prices—can not be deceptive because the prices are still bona fide as to at least a substantial number of purchasers. There is no evidence whatsoever that Aventis engaged in deceptive, unfair, and/or fraudulent conduct when it published wholesale list prices for the drugs at issue.

Nor can plaintiffs establish liability based on Aventis's reporting of AWP (or MSP) prior to 2001. Plaintiffs allege that Aventis engaged in a "scheme to inflate its reported AWPs," but plaintiffs can point to no evidence to support their contention that Aventis's AWPs were "inflated." Aventis at various times increased the wholesale list prices for its products, but those increases were always limited to a weighted average of the increase in the CPI. More importantly, the relationship between Aventis's wholesale list prices and the corresponding published AWPs were always consistent with well-known industry standards. The Court's expert, Dr. Berndt, explained that "it has been common knowledge among industry observers

that brand pharmaceutical firms typically sell self-administered single-source drugs to wholesalers at a price known as 'wholesale acquisition cost' (WAC) that in most cases is 16.67% to 20% less than AWP; this implies that AWP is typically 20% to 25% greater than WAC." (Report of Prof. Ernst R. Berndt, Feb. 9, 2005 at ¶ 15 (attached to Matye Decl. as Ex. D).) After reviewing the continued reliance on published AWP as a reimbursement benchmark, Dr. Berndt wrote: "The evolution of the AWP-WAC 'spread' for branded self-administered pharmaceuticals is . . . quite understandable, and apparently not the result of any sinister or nefarious conspiracies." (*Id.* at ¶ 23.) The evidence of the States' own understanding of AWP and their relation to acquisition costs, as detailed in defendants' joint memoranda of law in support of summary judgment, further supports the conclusion that Aventis did not engage in deceptive, unfair, or fraudulent conduct in connection with the reporting of AWP.

Finally, the AWP/MSPs Aventis reported were not "inflated" under the standards for liability set forth by plaintiffs' own expert. Dr. Hartman states that defendants allegedly engaged in a pricing scheme that "fraudulently increased the AWP of selected drugs . . . above the provider acquisition costs for which the AWP were a market signal." (Hartman Montana Decl. of June 13, 2006 at ¶ 3 (attached to Matye Decl. as Ex. E); Hartman Nevada Decl. of June 13, 2006 at ¶ 3 (attached to Matye Decl. as Ex. F).) In the MDL class action cases, Dr. Hartman advanced the theory that payers were misled by AWP only if the resulting "spreads" between AWP and provider acquisition cost exceeded the payers' expectations of spreads, and he determined that the threshold for determining liability under this theory was a 30% spread. While Dr. Hartman does not apply his expectations analysis in the Montana and Nevada cases, he does acknowledge that under his theory such expectations apply to all industry participants, including Montana and Nevada Medicaid. (Aug. 22, 2006 Deposition of Dr. Raymond Hartman,

32:12-21 (attached to Matye Decl. as Ex. H).) If Dr. Hartman were to apply his expectations analysis to determine liability here, using his own methodology to calculate spreads, he would find that for Aventis's self-administered drugs at issue, none of the published AWP's exceeded the 30% threshold. (Hughes Decl. at ¶ 11.)

In summary, the undisputed facts show that Aventis did not engage in deceptive, unfair, and/or fraudulent conduct in connection with the reporting of wholesale list prices and/or AWP's for the Aventis self-administered drugs at issue in these cases.

B. Aventis Did Not Engage in Deceptive, Unfair, or Fraudulent Marketing Activities.

Plaintiffs allege that Aventis engaged in a scheme to "market" the spread between AWP's and provider acquisition costs in order to "increase the market share of its drugs." But plaintiffs can point to no evidence whatsoever to support their allegation that Aventis "marketed the spread" or in any way used published AWP's in an attempt to increase its market share for the self-administered drugs at issue here.

In addition, plaintiffs' allegations that Aventis marketed the spread to increase its market share are again inconsistent with the theories of plaintiffs' own expert. Dr. Hartman states that the economic motivation for allegedly inflating the spread between the AWP of a drug and its cost was that "[t]he increased profits [from spreads] induced providers to move market share of the relevant drugs, the *raison d'être* of the AWP Scheme to the drug manufacturers." (Aug. 22, 2006 Deposition of Dr. Raymond Hartman, 55:5-9 (attached to Matye Decl. as Ex. H).) While Dr. Hartman has done no analysis in these cases to determine whether Aventis used its AWP's to induce providers to move market share (or whether any providers were so induced), he did opine in the MDL class action cases that a spread of AWP over acquisition costs in excess of 30% was necessary to move market share. (Hartman Decl., Dec. 15, 2005 at ¶ 59(e) (attached

to Matye Decl. as Ex. G).) Dr. Hartman confirmed this opinion in deposition testimony in these cases, noting that in the MDL class cases, he “found the 30 percent [spread] to be a conservative bound for an expectation for a drug that was not subject to the – the exploitation of spread for . . . to move market share.” (Aug. 22, 2006 Deposition of Dr. Raymond Hartman, 32:8-11 (attached to Matye Decl. as Ex. H).) As stated above, none of the Aventis self-administered drugs at issue here had spreads of over 30%, according to Dr. Hartman’s own methodology. Thus, even under Dr. Hartman’s own theory, Aventis would have been unable to use AWP to move market share for these drugs.

CONCLUSION

Because no reasonable jury could find that Aventis engaged in deceptive, unfair, or fraudulent pricing, price reporting, or marketing of the self-administered drugs at issue in these cases, the Court should grant Aventis’s motion for partial summary judgment.

Dated: February 8, 2007

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CERTIFICATE OF SERVICE

I here by certify that on February 8, 2007, copies of the foregoing Motion for Partial Summary Judgment were served on all counsel of record via ECF and Lexis/Nexis File & Serve.

/s/ Joseph G. Matye